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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/636,185	08/10/00	GERBER	GER-100XC1

023557
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HM12/1024

EXAMINER	
PATTEN, P	
ART UNIT	**PAPER NUMBER**
1651	9

DATE MAILED: 10/24/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

1- File Copy

PTO-90C (Rev. 11/00)

Office Action Summary	Application No. 09/636,185	Applicant(s) Gerber et al.
	Examiner Patricia Patten	Art Unit 1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☐ Responsive to communication(s) filed on _____.

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-30* is/are pending in the application.

4a) Of the above, claim(s) *12-27* is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1-11 and 28-30* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 6
18) ☐ Interview Summary (PTO-413) Paper No(s). _____
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other: _____

DETAILED ACTION

Election/Restriction

Applicant's election of Group I, claims 1-11 and 28 in Paper No. 8 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

With regard to claims 29 and 30; These claims were not originally present in the restriction requirement, however, it is agreed that these claims properly belong with Group I and therefore will be considered on the merits along with claims 1-11 and 28.

Claims 12-27 have been withdrawn from consideration as being drawn to a non-elected invention.

Claims 1-30 are pending in the application.

Claims 1-11 and 28-30 were presented for examination on the merits.

Claim Rejections - 35 USC § 112

The specification is objected to under 35 U.S.C. § 112, first paragraph, as failing to provide an adequate written description of the invention, failing to provide an enabling disclosure and failing to present the best mode contemplated by applicant for carrying out the invention without complete evidence either that the claimed biological materials are known and readily available to the public or complete evidence of the deposit of the biological material.

It is apparent that the microorganism(s) is/are required to practice the claimed invention. As a required element it/they must be known and readily available to the public or obtainable by a repeatable method set forth in the specification. If it/they is/are not so obtainable or available, the enablement requirements of 35 U.S.C. § 112, first paragraph, may be satisfied by a deposit of the microorganism(s). See 37 C.F.R. § 1.802.

The specification does not provide a repeatable process for obtaining the microorganism(s) and it is not apparent if the microorganism(s) is/are readily available to the public. The specification must contain the date that the microorganism(s) was/were deposited, the name of the microorganism(s) and the address of where the microorganism(s) was/were deposited.

If the deposit(s) has/have been made under the terms of the Budapest Treaty, then an affidavit or declaration by Applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney or record over his/her signature, and registration number, stating that the specific strain(s) has/have been deposited under the Budapest Treaty and that all restrictions imposed by the depositor on the availability to the public

of the deposited material will be irrevocably removed upon the granting of a patent, would satisfy the deposit requirements. See 37 C.F.R. § 1.808.

If the deposit(s) has/have not been made under the Budapest Treaty, then in order to certify that the deposit(s) meets the criteria set forth in 37 C.F.R. § 1.801-1.809, Applicant(s) may provide assurance of compliance by an affidavit or declaration, or by a statement by an Attorney of record over his/her signature and registration number, showing that:

(a) during the pendency of this application, access to the invention will be afforded to the Commissioner upon request;

(b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;

(c) the deposit(s) will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer;

(d) a viability statement in accordance with the provisions of 37 C.F.R. § 1.807; and

(e) the deposit will be replaced should it become necessary due to inviability, contamination or loss of capability to function in the manner described in the specification.

In addition, the identifying information set forth in 37 C.F.R. § 1.809 (d) should be added to the specification. See 37 C.F.R. § 1.803-1.809 for additional explanation of these requirements.

In the instant case, Applicants have not provided the ATCC number which would correspond to the deposited strain of 'helper factor.' Also, the address of the ATCC is incorrect (please use 10801 University Blvd. Manassas, VA 20110-2209).

Claims 2-11 and 29-30 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for growing Pasteuria endospores *in vitro* via introduction of a specific deposited 'helper factor' microorganism such as *Enterobacter cloacae* , does not reasonably provide enablement for the growth of Pasteuria with any strain of *Enterobacter cloacae*, or further from any other microbe, nor does it provide enablement for the use of a chemical derived from *Enterobacter cloacae* . The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to the invention commensurate in scope with these claims.

The factors to be considered in determining whether undue experimentation is required are summarized In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988). The court in Wands states: "Enablement is not precluded by the necessity for some experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.' " (Wands, 8 USPQ2d 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations." (Wands, 8 USPQ2d 1404). The factors to be considered

in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. While all of these factors are considered, a sufficient amount for a *prima facie* case are discussed below.

The Instant Specification as filed contains no teachings whereby other microbes, besides the microbe which was deemed 98% homologous to *Enterobacter cloacae* would work commensurate in scope with the claimed invention. Further, there is no teaching or guidance present in the Disclosure of what the 'chemical compound' 'helper factor' is, and how one of skill in the art would go about extracting or isolating such a substance.

The art of microbiology is extensively diverse and unpredictable.

With regard to the 'chemical compound' which is a 'helper factor'; sufficient guidance with regard to exactly what compound the HF-1 encompasses is not present in the Specification as filed. Although Applicant need not disclose the exact composition of the compound if it was not known at the time of filing, the skilled artisan should be able to reproduce the HF-1 by drawing to the information found in the Disclosure. However, no guidance is provided by which one would actually isolate or extract such a substance from the microbe which was found similar

to *Enterobacter cloacea*. Thus, it would require a substantial inventive contribution from one of skill in the art to ascertain what HF-1 is, and how to produce it/extract it/isolate it.

Claims 29 and 30 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for producing Pasteuria, does not reasonably provide enablement for producing any species of bacterium with the presently recited cultivation method. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Although the chemical 'helper factor' which was presumably produced by *Enterobacter cloacae* was found beneficial to *in-vitro* growth of Pasteuria spores, this success cannot be extrapolated to successful growth of other strains of bacteria without undue experimentation on the part of the skilled practitioner. The *Enterobacter cloacae* may act synergistically with Pasteuria, whereby the *Enterobacter cloacae* produces a compound which facilitates the growth of the Pasteuria; however, the art of microbiology is unpredictable as discussed *supra*. The chemical 'helper factor' produced by *Enterobacter cloacae* may actually prove detrimental to other strains of bacteria, lacking clear, sufficient guidance to the contrary.

In re Fisher, 427 F.2d 833, 166 USPQ 18 (CCPA 1970), held that

"Inventor should be allowed to dominate future patentable inventions of others where those inventions were based in some way on his teachings, since such improvements

while unobvious from his teachings, are still within his contribution, since improvement was made possible by his work; however, he must not be permitted to achieve this dominance by claims which are insufficiently supported and, hence, not in compliance with first paragraph of 35 U.S.C. 112; that paragraph requires that scope of claims must bear a reasonable correlation to scope of enablement provided by specification to persons of ordinary skill in the art; in cases involving predictable factors, such as mechanical or electrical elements, a single embodiment provides broad enablement in the sense that, once imagined, other embodiments can be made without difficulty and their performance characteristics predicted by resort to known scientific law; in cases involving unpredictable factors, such as most chemical reactions and physiological activity, scope of enablement varies inversely with degree of unpredictability of factors involved."

The inadequate disclosure coupled with a lack of representative examples and the art recognized unpredictability with respect to the art of microbiology preclude the making and use of compounds within the scope of the presently claimed invention by the skilled artisan without undue experimentation. It may be true the Applicant is able to make the invention, however, it is not seen the claims are set forth in clear, concise and exact terms to enable someone other than the Applicant to make the invention which is a requirement of the statute.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 9-10 and 28 are rejected under 35 U.S.C. 102(b) as being anticipated by Reise (1998) or Reise (1991).

Claims 1, 9-10 and 28 are drawn to a method for producing Pasteuria spores in vitro, whereby Pasteuria are grown in a growth medium and endospores are obtained therefrom. Claims are further drawn to wherein the growth medium does not contain an antibiotic, wherein the method is carried out without stirring and a composition comprising the endospore produced by the method of claim 1.

Reise (1998) and Reise (1991) disclosed methods for *in-vitro* cultivation of Pasteuria species. Reise (1998) specifically taught that various mediums such as Grace's Insect Medium, were utilized for producing Pasteuria species which subsequently propagated Pasteuria endospores. Reise (1991) also taught that a 'complex undefined medium containing 111 ingredients' was created in order to create Pasteuria spores.

Neither of the references disclosed the addition of antibiotics, nor where the medium was stirred during cultivation.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 9-11 and 28 are rejected under 35 U S.C. 103(a) as being unpatentable over Reise (1998) or Reise (1991). Claim 11 is drawn to where manganese sulfate or lipids are added to the medium to induce the production of endospores.

The teachings of Reise (1998) and Reise (1991) were discussed *supra*.

Media formulations which included manganese sulfides were routinely added to culture mediums to enrich the growing environment with essential trace metals which were known beneficial nutrients for microorganisms. The adjustment of particular conventional working conditions (e.g., using well known beneficial culture medium ingredients including lipids and minerals such as manganese sulfate, and/or adding or not adding an antibiotic thereto), is deemed merely a matter of judicious selection and routine optimization which

was well within the purview of the skilled artisan, as evidenced by both Reise teachings which utilized media with numerous nutritional additives to enrich the Pasteuria growth medium.

One of ordinary skill in the art would therefore have been motivated to have added manganese sulfate and/or lipids to a medium containing Pasteuria in order to supply said Pasteuria with additional nutrients thereby achieving increased growth rates.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Claims 2-8 and 29-30 are free of the art, however, are rejected under 35 U.S.C. 112 First Paragraph *supra*.

No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Patricia Patten, whose telephone number is (703)308-1189. The examiner can normally be reached on M-F from 9am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

CHRISTOPHER R. TATE
PRIMARY EXAMINER